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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/589,051	03/26/2007	Katja Berg-Schultz	22234 US (C038435/0199186	5471	
Stephen M. Har	7590 08/04/200 acz	EXAMINER			
BRYAN CAVE	E	MABRY, JOHN			
1290 Avenue of New York, NY			ART UNIT	PAPER NUMBER	
,			1625		
			MAIL DATE	DELIVERY MODE	
			08/04/2008	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		,	Application l	No. Applicant(s)					
Office Action Summary			10/589,051		BERG-SCHULTZ ET AL.				
			Examiner		Art Unit				
			John Mabry, l		1625				
Period fo	The MAILING DATE of this commur or Reply	nication appe	ars on the co	ver sheet with the c	orrespondence ad	ddress			
WHIC - Exter after - If NO - Failu Any r	ORTENED STATUTORY PERIOD F CHEVER IS LONGER, FROM THE IN Isions of time may be available under the provisions SIX (6) MONTHS from the mailing date of this com- period for reply is specified above, the maximum is the to reply within the set or extended period for reply teply received by the Office later than three months and patent term adjustment. See 37 CFR 1.704(b).	MAILING DAT s of 37 CFR 1.136 munication. tatutory period will y will, by statute, ca	TE OF THIS (a). In no event, I apply and will exause the application	COMMUNICATION nowever, may a reply be timpire SIX (6) MONTHS from on to become ABANDONE	I. lely filed the mailing date of this of (35 U.S.C. § 133).				
Status									
1) 又	Responsive to communication(s) file	ed on 29 Apr	il 2008						
	• • • • • • • • • • • • • • • • • • • •	2b)⊠ This a		final.					
—		<i>'</i> —			secution as to the	e merits is			
٥/ك	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Dispositi	on of Claims								
-		annlication							
	Claim(s) <u>1-17</u> is/are pending in the application.								
	4a) Of the above claim(s) <u>18-21</u> is/are withdrawn from consideration.								
·	Claim(s) is/are allowed.								
· ·	Claim(s) <u>1-17</u> is/are rejected.								
•	Claim(s) is/are objected to.	- 4: 1/	-1						
8)[_]	Claim(s) are subject to restrict	ction and/or e	election requ	irement.					
Applicati	on Papers								
9) 🗌 🤈	The specification is objected to by th	ne Examiner.							
10)	The drawing(s) filed on is/are	: а)∐ ассер	oted or b)□	objected to by the E	Examiner.				
	Applicant may not request that any object	ection to the dr	awing(s) be h	eld in abeyance. See	e 37 CFR 1.85(a).				
	Replacement drawing sheet(s) including	g the correction	n is required i	f the drawing(s) is obj	ected to. See 37 C	FR 1.121(d).			
11)	11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority u	ınder 35 U.S.C. § 119								
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 									
2) Notic 3) Inforr	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (I nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date 8/10/06.		4) 5) 6)	=	ite				

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DETAILED ACTION

Applicant is respectfully reminded that it is <u>required</u> that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

Examiner's Response

Applicant's response on April 29, 2008 filed in response to the Election/Restriction dated March 25, 2008 has been received and duly noted. The Examiner acknowledges Applicants' election of Group II with traverse. The Applicant requested that intra-claim restriction be withdrawn. Examiner has properly restricted Applicant's invention by properly breaking unity has communicated in Election/Restriction dated March 25, 2008.

Examiner reserved the right to further restrict if Applicant selected Group II. The Examiner has further restricted Group II as follows:

R1 and R2 = cyano (CN)

R3, R4, R5, R6 = H, C1-C10 alkyl, C2-C10 alkenyl, C2-C10 alkynyl, C3-C10 cycloakyl and C6-C10 aryl.

X =as disclosed in claims 2, 3, 4 and 5.

In view of this response, the status of the rejections/objections of record is as follows:

Specification Objections

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The Specification is objected to due to the structural drawings as mentioned immediately below in first 112-2nd rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The structures below have the following problems: The first two structures does not have the correct valency the specified nitrogen position. Does Applicant intend one lone pair of electrons, two lone pair of electrons, or a lone pair of electrons and a H bonded to nitrogen? Examiner suggests that Applicant correct valency of nitrogens specified.

The third and last structure has a covalent bond to potassium (K). If so, there would be valency issues with K, the carbon to which the K is bonded and the sulfate counter ion. What bonding arrangement does Applicant intend? Examiner suggests that Applicant correct valency and bonding of said structure.

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The term "tristromethamine ion" in claim 11 is an indefinite term. The term "tristromethamine ion" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This term is not defined in the Specification. Examiner additionally searched for this chemical term in several texts that are widely accept in the art and found no such term.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is claiming compounds of formula I wherein Y is "tristromethamine ion". There is no evidence/written description in the specification for this variable. Additionally, there are no examples or reduction to practice of said groups.

According to the MPEP §2163 I. A. "the issue of a lock of adequate written description may arise even for an original claim when an aspect of the claimed invention has been described with sufficient particularity such that one skilled in the art would recognize that the Applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art." The MPEP states in §2163 II 3 ii) "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see I) (A), above), reduction to drawings (see I)(B), above), or by disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see I)(C), above). See Eli Lilly, 119 F.3d at 1568, 43, USPQ2d at 1406."

As discussed above the phrase "tristromethamine ion" is not art recognized in the specification. According to the MPEP §2163.02 Standard for Determining Compliance With the Written Description Requirement,

"The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed". In re Gosteli, 872, F.2d 1008 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of filing date sought, he or she was in possession of the invention, an that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter". Ralston Purina Co. v. Far-Mar-Co., Inc., 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In re Kaslow, 707 F.2d 1366, 1375 217 USPQ 1089, 1096 (Fed. Cir. 1983))."

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for R3, R4, R5, R6 being H and unsubstituted alkyl and alkenyl and X being alkyl optionally substituted with O, N, S, pyridinyl, cycloalkyl and phenyl does **not** reasonably provide enablement for R3, R4, R5, R6 being all alkynyl, cycloalkyl and aryl as claimed (substituted or unsubstituted) and all possibilities as disclosed in claims 2, 3, 4 and 5.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The Specification does <u>not</u> reasonably provide enablement for R3, R4, R5, R6 being all alkynyl, cycloakyl and aryl as claimed (substituted or unsubstituted) and all possibilities as disclosed in claims 2, 3, 4 and 5. Pages 14-17 of the Specification describe starting materials and methods for synthesis of compounds

wherein R3, R4, R5, R6 being H and unsubstituted alkyl and alkenyl and X being alkyl optionally substituted with O, N, S, pyridinyl, cycloalkyl and phenyl, but does not describe or list any reagents wherein compounds can be used to synthesis compounds where R3, R4, R5, R6 and X as listed above.

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

- (1) Breadth of claims: Scope of the compounds. Owing to the range of many variables, millions of highly substituted 1,4-dihydropyridine derivative compounds are embraced.
- (2) The nature of the invention: The invention is a highly substituted 1,4-dihydropyridine derivative compounds.

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(3) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and chemical reactivity (which is affected by determinants such as substituent effects, steric effects, bonding, molecular geometry, etc) is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

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(4) Direction or Guidance: That provided is very limited. Applicant shows a general synthesis of compounds of application's general formula I. Pages 14-17 of the Specification describes starting materials and methods for synthesis of compounds wherein R3, R4, R5, R6 being H and unsubstituted alkyl and alkenyl and X being alkyl optionally substituted with O, N, S, pyridinyl, cycloalkyl and phenyl, but does not describe or list any reagents wherein compounds can be used to synthesis compounds where R3, R4, R5, R6 and X as listed above. There is limited evidence in the Specification of the example compounds that only covers no or a small portion of the substituents claimed of formula. Thus, there is no specific direction or guidance regarding said compounds specifically mentioned in Scope.

The availability of the starting material that is needed to prepare the invention as claimed is at issue here...As per MPEP 2164.01 (b). A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to a make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of

microorganism and when the microorganism is available only after extensive screening. The Court *in re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made it clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

(5) State of the Prior Art: These compounds are substituted 1,4-dihydropyridine derivative compounds wherein R3, R4, R5, R6 being H and unsubstituted alkyl and alkenyl and X being alkyl optionally substituted with O, N, S, pyridinyl, cycloalkyl and phenyl, which are well documented in the art. So far as the examiner is aware, no substituted 1,4-dihydropyridine derivative compounds of general formula I wherein R3, R4, R5, R6 being all alkynyl, cycloakyl and aryl as claimed (substituted or unsubstituted) and all possibilities as disclosed in claims 2, 3, 4 and 5 of any kind have been made or used.

It is not trivial to experimentally interchange any and all of the many substituents that exist. As described by F. Zaragoza Dörwald, most organic syntheses fail initially and chemical research is highly inefficient due to chemists spending most of their time "finding out what went wrong and why". Therefore, most syntheses of organic compounds are labor-intensive and demanding. Additionally, most final synthetic routes

to desired organic molecules are usually very different from initially planned routes. A highly skilled chemist can agree that for many successful organic compounds made, many failures are encountered and experimental repetition is common. This also contributes to the burden and unpredictability of the syntheses of said compounds. (see "Side Reactions in Organic Synthesis: A Guide to Successful Synthesis Design" 2005 Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim.

- (6) Working Examples: Applicant shows examples pages 9-17 but no working examples were shown wherein R3, R4, R5, R6 and X equal aforementioned substituents have been made or used of any kind.
- (7) Skill of those in the art: The ordinary artisan is highly skilled, e.g. a masters or PhD level chemist.
- (8) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provide, and the lack of working examples, the Applicant has shown lack of enablement for the groups noted.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the

application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsubayashi et al (Inorganica Chemica Acta 1982, 63, 217-224 – PTO-1449).

Matsubayashi discloses compounds and compositions of Formula I where R3, R4, R5, R6=H, R1/R2=CN, X=C1 alkylene group containing 2 heteroatoms (N) and Y=tetrakis(phenylisocyanide)rhodium(I) (see compound below and page 217, right column).

Claims 1-5, 9 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanaka et al (Bull. Chem. Soc. Jpn. 1984, 57, 2198-2202).

Tanaka discloses compounds and compositions of Formula I where R3, R4, R5, R6=H, R1/R2=CN, X=C1 alkylene group containing 2 heteroatoms and Y as disclosed below (see page 2198, left column).

Claims 1-5, 9 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Urayama et al (Synthetic Metals 1987, 19, 469-474 – PTO-1449).

Urayama discloses compounds and compositions of Formula I where R3, R4, R5, R6=H, R1/R2=CN, X=C1 alkylene group containing 2 heteroatoms and Y as disclosed below (see Table 1, page 471).

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$$\mathbf{Y} = \begin{bmatrix} \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{Y} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S} \\ \mathbf{S} & \mathbf{S} & \mathbf{S} & \mathbf{S}$$

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10, 12-14 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg-Schultz (WO 03/068183 A1 – PTO-1449).

The instant application claims compounds and compositions of Formula I wherein where R3/R4=H, R5/R6=CH3, R1/R2=CN, X=C1-C20 alkylene that optionally contain 1-10 heteroatoms and Y=counter ion.

Scope & Content of Prior Art MPEP 2141.01

WO '183 discloses compound and compositions of Formula I wherein R3/R4=H, R5/R6=CH3, R1/R2=CN, X=C1-C20 alkylene that optionally contain 1-10 heteroatoms (as shown below and pages 1-2, Formula I and species therein).

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Differences between Prior Art & the Claims MPEP 2141.02

WO '183 differs from instant application at the Y position: WO '183's compounds as shown above are neutral compounds of Formula I versus Applicant's Y being a counter ion. However, WO '183 teaches that the addition of electrolytes into the composition of his invention can potentially change the behavior of the hydrophobic emulsifier. WO '183 goes on to suggest that these emulsions may contain one of several salts which may include anions such as (a) chloride, sulfate, carbonate, borate or aluminate and (b) organic anions such as but not limited to lactate, acetate, benzoate, etc. (see page 12, lines 8-18).

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Furthermore, the genus of Formula I, page of the reference by WO '183 teaches:

(f) X is a group $-(R^9-O-R^{10})_x$ -O- $(R^{11}-O-R^{12})_y$ -, wherein R^9 , R^{10} , R^{11} and R^{12} are, independently, methylene, ethylene or propylene, and x and y are, independently 1,2 or 3.

(see lines 31-32, page 3).

Berg-Schultz's genus also teaches:

(c) R^3 and R^4 are hydrogen and R^5 and R^6 are alkyl or cycloalkyl. (see lines 28, page 3).

Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413

It would be obvious for one of ordinary skill in the art to combine the disclosed compounds along with the teachings of Formula I of WO '183 in order to achieve the instant invention. In combination with the disclosed species and teachings as mentioned above, one of ordinary skill would be further motivated to use the reference of WO '183 because it's utility is used to as cosmetic or dermatological sunscreen compounds and composition (see page 1, first paragraph) as claimed by instant application.

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should

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be made explicit. The Court quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." KSR, 550 U.S. at____, 82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) "Obvious to try" choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. See MPEP § 2143 for a discussion

of the rationales listed above along with examples illustrating how the cited rationales may be used to support a finding of obviousness. See also MPEP § 2144- §2144.09 for additional guidance regarding support for obviousness determinations.

The aforementioned reasons above describe rationales that support a conclusion of obviousness based upon the KSR International Co. *v.* Teleflex Inc. decision. At least letters (A)-(G), rationale is supported above.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 12-14 and 16-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 9-19 of copending Application No. US 2005/0019278 A1 (10/494,500) - WO equivalent WO 03/068183 A1 – PTO-1449. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following.

The instant application claims compounds and compositions of Formula I wherein where R3/R4=H, R5/R6=CH3, R1/R2=CN, X=C1-C20 alkylene that optionally contain 1-10 heteroatoms and Y=counter ion.

Scope & Content of Prior Art MPEP 2141.01

US '278 discloses and claims compound and compositions of Formula I wherein R3/R4=H, R5/R6=CH3, R1/R2=CN, X=C1-C20 alkylene that optionally contain 1-10 heteroatoms (as shown below and pages 1-2, Formula I and species therein).

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Differences between Prior Art & the Claims MPEP 2141.02

US '278 differs from instant application at the Y position: US '278's compounds as shown above are neutral compounds of Formula I versus Applicant's Y being a counter ion. However, US '278 teaches that the addition of electrolytes into the composition of his invention can potentially change the behavior of the hydrophobic emulsifier. US '278 goes on to suggest that these emulsions may contain one of several salts which may include anions such as (a) chloride, sulfate, carbonate, borate or aluminate and (b) organic anions such as but not limited to lactate, acetate, benzoate, etc. (see paragraph 86).

Furthermore, the genus of Formula I, page of the reference by US '278 teaches:

[0008] X is a moiety R⁷, when m is 1; and is alkylone or poly(exyalkylone) when m is 2; and

(see paragraph 8),

US '278's genus also teaches:

[0009] R⁷ is hydrogen, alkyl, cycloalkyl, alkoxyalkyl or arvl.

(see paragraph 9).

Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413

It would be obvious for one of ordinary skill in the art to combine the disclosed compounds along with the teachings of Formula I of US '278 in order to achieve the instant invention. In combination with the disclosed species and teachings as mentioned above, one of ordinary skill would be further motivated to use the reference of US '278 because it's utility is used to as cosmetic or dermatological sunscreen compounds and composition (see page 1, first paragraph) as claimed by instant application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant is respectfully reminded that it is <u>required</u> that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to John Mabry, PhD whose telephone number is (571)

270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's

primary examiner can be reached at (571) 272-0684, first, or the Examiner's supervisor,

Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry/ Examiner Art Unit 1625

> /Rita J. Desai/ Primary Examiner, Art Unit 1625